IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 4:09-CV-11340 (FDS)
CENTOCOR ORTHO BIOTECH, INC. and CENTOCOR BIOLOGICS, LLC,	)	
Defendants.	)	

CENTOCOR'S REPLY ON ITS MOTION FOR RECONSIDERATION OF TWO ASPECTS OF THE MARCH 9, 2012 ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

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I. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT CERTAIN CLAIMS OF THE 485 PATENT ARE INVALID FOR LACK OF WRITTEN DESCRIPTION

A. Brief Summary Of Centocor's Argument In Reply

The Court found that there is a dispute of fact as to whether the description of some antibodies that bind to the p40 subunit of IL-12 is sufficient to show possession of an invention to *any* antibody that binds to this p40 subunit – regardless of whether the p40 subunit is part of IL-12 or part of the p40/p19 interleukin that was later identified as IL-23. The existence of this factual dispute is the focal point of Abbott's opposition brief. Abbott has missed the point that Centocor has asked the Court to reconsider.

Centocor has *not* challenged the Court's conclusion on this subject matter in its motion for reconsideration. What Centocor has asked the Court to reconsider is whether, accepting for the purpose of this motion that the patent does describe some antibodies that bind to the p40 subunit of IL-12/IL-23, that description is sufficient to meet the written description requirement for claims to any antibody that binds to *any* interleukin that includes a p40 subunit. Centocor is challenging whether that description supports *antibodies that do not bind to the p40 subunit but can bind to some other unidentified part of an undefined antigen,* and *including antibodies that bind to p40-containing interleukins (antigens) that are nowhere described in the patent – and may not even have been discovered yet*.

The point is probably best illustrated through examples. Suppose there is a p40/p99 interleukin – interleukin XX – that is identified five years from now. If someone isolates an antibody that binds to the p99 subunit of that antigen XX, could any reasonable jury conclude that the 485 patent specification provides written support for such a p99-binding antibody? No. Could any reasonable jury conclude that the 485 patent specification provides written support for an anti-XX antibody when the anti-XX antigen is nowhere described in the 485 patent? No.

The reason reconsideration is now requested is because there are no facts that could support a conclusion that the 485 patent inventors were in possession of an invention to something that was not known to exist at the time they filed their patent application.

Since Abbott does not dispute that the only antibodies disclosed in the patent are antibodies that bind to the p40 subunit of IL-12 and IL-23,[1] there are no facts of record that would preclude summary judgment of invalidity of the claims that are the subject of Centocor's request for reconsideration. Rather, the denial of summary judgment for these claims stems from the Court's apparent reliance on the erroneous premise that all of the 485 patent claims are *limited* to antibodies that bind to the p40 subunit of either IL-12 or IL-23. Because this is not true for the subset of claims for which Centocor now seeks reconsideration, there is a manifest error of law reflected in the Court's opinion. Centocor, therefore, now asks the Court to reconsider its opinion on the written description support, or lack thereof, for claims that are *not* limited to antibodies that bind to the p40 subunit of IL-12 and/or IL-23.

B. The Patent's Disclosure of Antibodies That Bind to the p40 Subunit of IL-12 and/or IL-23 Was Central to the Court's Opinion

The fact that the patent specification discloses antibodies that bind to the p40 subunit of IL-12 and/or IL-23 was central to the Court's opinion on written description. The Court described the 485 patent claims as encompassing "antibodies that bind to the p40 subunit of both IL-12 and IL-23" (Order at 44), and specifically referred to the fact that this "specific p40 subunit to which the disclosed antibodies bind" was a described feature that the IL-12 and IL-23 antigens have in common (*id*. at 46-47, 48). The Court relied on the expectation stated in the 485 patent that p40-binding antibodies would bind to p19/p40, on the purported disclosure in the

[1] Although Centocor disputes that the 485 patent describes antibodies that bind IL-23, since Abbott relied only on *post-filing* date data to show that any of the disclosed antibodies actually bind IL-23, that is a disputed fact. But Centocor is not rearguing that point here.

patent specification of antibody species that bind to the p40 subunit of IL-12, and on literature purportedly describing IL-23, the name later given to p19/p40 (*id*. at 46-49). The Court also relied on evidence from Abbott's expert, Dr. Marks, where he identified antibody species disclosed in the patent that allegedly bind to the p40 subunit of IL-12 (*id*. at 48, including footnote 40). Abbott has even previously characterized Dr. Marks statements as relating to species of antibodies that bind to this p40 subunit (D.I. 259 at 8-9).

These findings were central to the Court's conclusion that there is at least a dispute of fact about the sufficiency of written description for the genus of antibodies that bind to the p40 subunit of IL-12 and/or IL-23. Again, Centocor is not presently challenging the Court's summary judgment order on this basis. But the logic of the Court's reasoning does not follow for the subset of claims that are the subject of the current motion for reconsideration. Centocor is asking the Court to reconsider whether there are any facts of record that could support a claim that the inventors were in possession of any antibody that binds to any interleukin that includes a p40 subunit – when the antibody is not required to *bind* to the p40 subunit of IL-12 and/or IL-23.

C. The Subject Claims Are Not Limited To Antibodies That Bind to the p40 Subunit of IL-12 or IL-23

As set forth in greater detail in Centocor's motion for reconsideration, claims 15, 18, 25, and 26 of the 485 patent are directed, *inter alia*, to antibodies capable of binding to an interleukin that has a p40 subunit, but they are not limited to antibodies that *bind* to that p40 subunit. Instead, the claims are broad enough to cover antibodies that bind, for example, to the p99 subunit of the hypothetical, undisclosed, undiscovered antigen XX mentioned above. But Abbott does not dispute that there is no disclosure in the patent concerning antibodies that bind anything other than a p40 subunit. Because disclosing antibodies that bind to a p40 subunit does not

suggest any expectation one way or the other about binding to another subunit, the full scope of claims 15, 18, 25, and 26 cannot be visualized from the patent disclosure.

Similarly, claims 1, 11, 15, 19, 24, 25, and 26 are not limited to antibodies that bind to the target antigen IL-12 or p19/p40 (IL-23). These claims only specify that the antibody is "capable" of binding to the p40 subunit of IL-12, whether or not it is in complex with p35 (to make IL-12) or with p19 (to make IL-23).[2] They do not limit the target antigen to IL-12 or IL-23 and, therefore, encompass antibodies capable of binding to interleukins that have still not been identified, but happen to share a common p40 subunit with IL-12. But again, it is undisputed that there is no disclosure in the patent concerning antibodies that bind anything other than IL-12 and, arguably, the p40/p19 complex now known as IL-23. Disclosing antibodies that bind to IL-12 or IL-23 does not suggest any expectation one way or the other about binding to another undisclosed antigen. The full scope of claims 1, 11, 15, 19, 24, 25, and 26 cannot be visualized from the description in the patent and therefore have no written description in the specification.

D. Abbott Does Not Dispute That The Only Antibodies Disclosed In The Patent Bind To The p40 Subunit of IL-12 and/or IL-23

Abbott does not dispute that the only antibodies disclosed in the patent are antibodies that bind to the p40 subunit of IL-12 and/or IL-23. Indeed, Abbott emphasizes this point in its opposition brief in stating that "[t]he '485 patent specification demonstrates that [the] disclosed antibody species bind to the p40 subunit of IL-12, and describes why these disclosed antibody species would also be expected to bind to IL-23 – that is because both IL-12 and IL-23 share a

[2] Abbott's statement (Abbott Opp. Br. at 6, n.3) that claims 1 and 11 are somehow limited to antibodies that bind to IL-12 is flatly wrong, as shown by the language of the claims themselves. Claim 1 recites antibodies that are "capable of binding to an epitope of the p40 subunit of IL-12." (Ex. 2 at 381:33-36). But that p40 subunit need not be in the p40/p35 complex that comprises IL-12. That can be seen from claim 2, which depends from claim 1, and recites antibodies that are capable of binding "when the p40 subunit is bound to the p35 subunit of IL-12." (*Id*. at 381:37-40). Claim 11 depends from claims 1 and 2, and the p40 subunit in claim 11 is therefore, like claim 1, not required to be in a p40/p35 complex. (*Id*. at 382:40-44).

common p40 subunit" (Abbott's Opp Br. at 7). Disclosing antibodies that bind to the p40 subunit shared by IL-12 and IL-23 does not suggest that the disclosed antibodies would be "expected" to bind to any interleukin that includes this subunit, including interleukins that have not yet been identified.

So, on the critical factual point underlying Centocor's motion for reconsideration, the parties agree. There is no disclosure in the patent of *other* target antigens, there is no attempt to identify such other antigens by structure, nor any attempt to describe antibodies that do or could be expected to bind to these undefined antigens. The outcome here might be different if the asserted claims identified the antibody by structure (*e.g.*, the amino acid sequence of the antibody itself), and that structure was later found to bind to a newly discovered antigen. But that is not the case here. The subject claims in the 485 patent do not claim the antibodies by their structure, but rather by a function - their ability to bind to an antigen. The patent cannot evidence that the inventors invented, or were in possession of, antibodies to antigens that are neither defined nor described – or may not even have yet been discovered. The full scope of the claimed antibodies encompassed by the claims cannot be visualized if the target to which they bind is not even known. There is no description in the patent that the applicants invented or were in possession of antibodies that bind to any subunit of an antigen, as long as the antigen happens to include a p40 subunit.

As there is no evidence from which a reasonable jury could conclude that, as of March 2000, the 485 patent applicants were in possession of a genus of antibodies that goes beyond antibodies that bind to the p40 subunit of IL-12 and IL-23, the full scope of the claimed antibodies encompassed by Claims 1, 11, 15, 18, 19, 24, 25, and 26 of the 485 patent cannot be

visualized from the patent disclosure. These claims are, as a matter of law, invalid for lack of written description.

II. CENTOCOR REQUESTS RECONSIDERATION OF THE COURT'S DENIAL OF SUMMARY JUDGMENT THAT THE COMPOSITION CLAIMS ARE INVALID AS ANTICIPATED BY CENTOCOR'S PRIOR INVENTION

A. Brief Summary Of Centocor's Argument In Reply

Centocor's request for reconsideration is based on the premise that the summary judgment ruling reflects an error of law because Abbott cannot prove an invention date for its Composition Claims prior to the time that all of the named joint inventors participated in the conception of the claimed invention. Abbott's opposition brief suggests that Centocor is arguing for an "exception" to the law based on a legal theory that "would turn existing Federal Circuit law of priority on its head." (Abbott Opp. Br. at 12, 11). To the contrary, however, it is the ***rule*** that an invention only becomes an "invention" after it has been conceived by the inventors. *Cooper v. Goldfarb*, 154 F. 3d 1321, 1327 (Fed. Cir. 1998) ("Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice."). Here, Dr. Friedrich contributed to the conception of the Composition Claims – but could not have done so until at least August 1998. Accordingly, the invention defined in the Composition Claims cannot have been made prior to that time. Centocor respectfully requests reconsideration of the denial of its motion for summary judgment on these grounds.

B. An Invention Is Conceived Only After The Inventors Have Provided Their Contribution

Abbott's argument in opposition to Centocor's motion is essentially this: If Abbott can show that each of its claims covers a single species that was made by a *subset* of the joint inventors, then the date that single species was made is automatically the invention date for any

claims that are thereafter conceived by a *larger* group of inventors, so long as the claims also cover the first species. Abbott would argue that this is true even if the subset of inventors that came up with the first species never once thought to make the invention broader in any way whatsoever. That is not the law.

"Different claims of a patent may have different dates of invention." *Section-By-Section Analysis: Patent Law Amendments of 1984*, 130 Cong. Rec. H10525 (1984). In other words, each claim defines a ***separate invention*** and each separate invention may have its own invention date. In this regard, Abbott asks the question:

> Why . . . would a single inventor who made species "A" and then species "B" be entitled to rely on the date species A was reduced to practice to support a genus claim, while an inventor that joined with a second inventor to make species "B" would be entitled only to the later date.

(Abbott Opp. Br. at 13). The answer to this is quite simple. The reason the invention with the "second inventor" may only rely on the date species "B" was made was because presumably the second inventor contributed to the conception of an invention that is now defined to include "species B." It was only once he provided that conception – species "B" – that there was an "invention" of a scope that is now defined by the claims to include species "B." In the scenario of the single inventor, it may be possible for the inventor to show that the entire claimed genus was conceived at the time he created species "A" and nothing else inventive was needed.

Abbott's hypothetical, as well as its briefing on this issue, fails to recognize the distinction of joint inventorship. With the case of joint inventors there is ***necessarily*** additional inventive contribution that is provided to the invention defined by the claims. There can be no invention until that inventive contribution is provided, and that inventive contribution cannot be provided until the inventors have collaborated. *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1303 (Fed. Cir. 2010) ("The interplay between conception and collaboration requires that each

co-inventor engage with the other co-inventors to contribute to a joint conception."). Abbott's reliance on cases like *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989) and *In re Stempel*, 241 F.2d 755, 759-60 (C.C.P.A. 1957), do not help it on this point because in those cases, there was no suggestion that the invention date sought was a date prior to the time the inventors began their collaboration. Abbott has provided no case law that remotely suggests that it is proper to give the invention defined by a patent claim an invention date prior to the time the *complete* conception of the claim occurred.

There is no dispute that Dr. Friedrich did not join the project until August 1998. Thus, his inventive contribution to the Composition Claims could not have occurred until after that time. Thus, the invention of the Composition Claims cannot have occurred before August 1998. Centocor's undisputed invention date of April 1998 for Stelara, therefore, invalidates the claims under 35 U.S.C. 102(g).

C. Abbott Still Does Not Contend That Inventorship Is Incorrect

In an attempt to confuse the issue, Abbott states that "the question of inventorship does not speak to the validity of the issued patent" and that inventorship can be corrected (Abbott Opp. Br. at 15). But noticeably missing is any statement that inventorship is, in fact, incorrect. Abbott has never contended that Dr. Friedrich is not an inventor on the Composition Claims. Abbott, of course, has had plenty of opportunity to reassess its own documents and lab notebooks to determine again whether Dr. Friedrich is a proper inventor. In spite of this opportunity, Abbott has never suggested that Dr. Friedrich was improperly included. Abbott's hypothetical does not preclude the grant of summary judgment.

D. There Are No Fact Issues Preventing The Grant Of Centocor's Motion

There are no issues of fact that prevent the Court from granting Centocor's motion for summary judgment of invalidity of the Composition Claims. As the Court properly stated in its

Order on Summary Judgment, "[f]or purposes of this motion, the Court will . . . assign Centocor's invention the priority date of April 30, 1998." (Order at 61). Although Centocor's invention date may be earlier, it was proper for purposes of the motion to assign Centocor that invention date because, as Abbott's responses to Centocor's statement of undisputed facts prove, there is not a single factual dispute regarding the work that Centocor performed to invent Stelara and that this work was completed no later than April 1998.

Abbott's only attempt to create a fact dispute relates to its argument that "Centocor ['s] inventors failed to recognize and appreciate all the required properties" as set out in the Composition Claims by April 30, 1998. As explained in detail in Centocor's Reply to its Motion for Summary Judgment No. 6 (D.I. 295), such recognition, however, is not required under the law. *See Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm., LP*, 661 F.3d 1378, 1384 (Fed. Cir. 2011) (The prior inventor does not need to conceive of its invention "using the same words as the patentee would later use to claim it."). Summary judgment that the Composition Claims are anticipated is appropriate on this record.

III. CONCLUSION

Centocor respectfully asks that the Court reconsider two aspects of its March 9, 2012 Order on Cross-Motions for Summary Judgment, as discussed above. Upon reconsideration, Centocor requests that the Court grant (1) summary judgment that Claims 1, 11, 15, 18, 19, 24, 25, and 26 of the 485 patent are invalid for lack of written description, and (2) summary judgment that the composition claims are invalid as anticipated under 35 U.S.C. §102(g)(2).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing

CENTOCOR'S REPLY ON ITS MOTION FOR RECONSIDERATION OF TWO ASPECTS OF THE MARCH 9, 2012 ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

was electronically mailed to counsel of record on April 13, 2012 through the Court's ECF notification system.

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